SEP - 4 2001

Exhibit D

510(k) Summary K011854

Submitted by: Daniel J. Manelli
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2000 M Street, NW (Suite 700)
Washington, DC 20036

Telephone: 202-261-1000

On behalf of Tokuyama America, Inc.
510(k) Submission: Tokuyama M Bond
August 10, 2001

The product is a self cured adhesive resin cement. It is intended for use in adhesion and fixation between tooth and prosthesis, tooth and tooth, and between two or more prostheses. Clinical applications include the cementation of inlays, onlays, crowns, metal posts and cores and similar applications.

The product is for use only by dental practitioners; it is not intended for OTC use. It contains materials that pose no health hazard when used according to directions and has received the approval of the Japanese Government. It is substantially equivalent to various marketed dental cement products, including the following:

Bistite II SC (Tokuyama)	K991711
C&B Metabond (Parkhill)	K960464
Panavia 21 (Kurarey)	K933030

The use of the product is contra-indicated for patients who are hypersensitive to methacrylate monomers. It should not be allowed to come into contact with skin, mucosal membrane, eyes or clothing. Should contact with the eyes occur, the eyes should be thoroughly flushed with water followed by immediate contact with a physician.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Tokuyama America, Incorporated
C/O Mr. Daniel J. Manelli
Attorney
Manelli, Dension & Selter, P.L.L.C
2000 M Street Northwest, Suite 700
Washington, DC 20036

Re: K011854
Trade/Device Name: Tokuyama M-Bond
Regulation Number: 872.3275
Regulatory Class: II
Product Code: EMA
Dated: June 13, 2001
Received: June 13, 2001

Dear Mr. Manelli:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit C

510(k) Number (if known): K011854

Device Name: Tokuyama M - Bond

Indications For Use:

For use as a dental cement for adhesion and fixation between tooth and prosthesis, tooth and tooth, and between two or more prostheses.

(Please Do Not Write Below This Line - Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
General Hospital Devices
Number K011854

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)